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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,739	04/09/2004	Gabor Tigyi	RxB-001	2451
41546	7590	10/09/2009		
DONNA J. RUSSELL 1492 ANTHONY WAY MT. JULIET, TN 37122			EXAMINER OLSON, ERIC	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 10/09/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/821,739

Applicant(s)

TIGYI ET AL.

Examiner

ERIC S. OLSON

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4, 12, 13, 20 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

This office action is a response to applicant's communication submitted June 9, 2009 wherein claims 20 and 23 are amended. This application claims benefit of provisional application 60/462274, filed April 11, 2003.

Claims 3, 4, 11, 12, 20, and 23 are pending in this application. Claims 3, 4, 11, and 12 are withdrawn from consideration as directed to a non-elected invention.

Claims 20 and 23 as amended are examined on the merits herein.

Applicant's amendment submitted June 9, 2009, with respect to the rejection of instant claim 20 under 35 USC 102(e) for being anticipated by Szarek et al., has been fully considered and found to be persuasive to remove the rejection as claim 20 no longer recites phosphoryl serine. Therefore the rejection is withdrawn.

Applicant's amendment submitted June 9, 2009, with respect to the rejection of instant claims 20 and 23 under 35 USC 102(b) for being anticipated by Scolnick, has been fully considered and found to be persuasive to remove the rejection as claims 20 and 23 no longer recite fatty alcohol phosphates. Therefore the rejection is withdrawn.

Information Disclosure Statement

The listing of references in the specification found on pp. 47-48 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP

§ 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the abbreviation "PPARy" without defining what this abbreviation stands for. Therefore the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US pre-grant publication 2003/0130237, cited in PTO-892) in view of Siess. (Reference included with PTO-892)

Miller et al. discloses a group of glycerol phosphate and pyrophosphate compounds. (p. 4 paragraphs 0031-0044) These compounds inhibit the lysophosphatidic acid (LPA) receptor and are useful for treating cancer and cell proliferation and promoting wound healing. (p. 4 paragraph 0046 - p. 5 paragraph 0050) Compounds specifically exemplified include diacylglycerol pyrophosphates, serine phosphoric acids, and monoacylglycerol diphosphates. (p. 8 paragraph 0132 - p. 9 paragraph 0135) Miller et al. does not disclose a method specifically comprising administering these compounds to a patient who is undergoing neointima formation, for example a patient having atherosclerosis.

Siess et al. discloses a study of the effects of oxidized LDL in platelet and endothelial cell activation. (p. 6931 right column first paragraph) Lysophosphatidic acid (LPA) was identified as the platelet activating component of oxidized LDL. (p. 6933 left column last paragraph - right column first paragraph) LPA induced morphological changes in endothelial cells (p. 6935 left column third paragraph) and was found in

atherosclerotic lesions. (p. 6935 left column last paragraph) LPA is seen to be involved in the pathogenesis of atherosclerosis and LPA inhibition is suggested as a strategy for treatment of atherosclerosis. (p. 6395 right column second paragraph - p. 6396 left column third paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the LPA inhibitors of Miller et al. to inhibit the pathogenesis of atherosclerotic lesions in a patient. One of ordinary skill in the art would have been motivated to do so because Siess et al. discloses that LPA is the component of oxidized LDL that is involved in the pathogenesis of atherosclerosis. One of ordinary skill in the art would have reasonably expected success because Miller et al. already discloses that these compounds are suitable for administration as therapeutic agents.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
10/2/2009